SEP 30 2004

K042364

**510(k) Summary of Safety and Effectiveness**

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|---|---|
| Company Name: | LaMont Medical, Inc. |
| Device Name: | PANBUS® Digital EEG and Sleep Acquisition Devices |
| 510(k) Sponsor: | LaMont Medical, Inc. |
| 510(k) Contact: | Tony Montgomery<br>President and CEO<br>LaMont Medical, Inc.<br>555 D'Onofrio Drive<br>Madison, WI 53719 |
| Phone: | (608) 827-9000 |
| Fax: | (608) 827-8600 |
| Summary Date: | September 24, 2004 |
| Trade Name: | PANBUS® Digital EEG and Sleep Acquisition Devices |
| Common Name: | Electroencephalograph |
| Classification Name: | Electroencephalograph, CFR 882.1400, Product Code: GWQ, Class II OLV |
| Predicate Device: | K990522 WARATAH and CARDINAL Digital EEG and Sleep Acquisition Devices<br><br>K023771Neuroscan SynAmps[2] |

**1.0 Description of Device**

Like the predicate WARATAH® and Cardinal® Digital EEG and Sleep Acquisition Devices (WARATAH® Devices), the PANBUS® Digital EEG and Sleep Acquisition Devices (PANBUS® Devices) are provided to Original Equipment Manufactures (OEM) for creation of an electroencephalography (EEG) recording system. Significant PANBUS® Devices are:

1) Personal computer (PC) interface board;
2) Electrode interface connection (Jackbox);
3) Communication protocol and port (PANBUS);
4) Amplifier(s);
5) Electrode lead wire sets.

## 1.2 Clinical Application

The PANBUS® Devices are used in hospital and clinical environments where recording of EEG patterns and sleep (polysomnography) are of clinical interest. The user applies commercially available EEG electrodes to the patient in an internationally recognized pattern (10-20) recommended by the PANBUS® Devices labeling and their clinical standards.

Other sensors may be applied to the patient. These sensors support Polysomnography (PSG) recording. Typical PSG signals include:

1. Air flow,
2. Respiration effort,
3. Limb movement.

These signals can be interfaced to the PANBUS® amplifiers.

## 2.0 Intended use of Device

The intended uses of the modified devices are the same as the predicate system:

- For long term unattended EEG or other electrophysiological signal monitoring and recording.

- This device is intended for use by physicians skilled in electroencephalography. These individuals are typically Board Certified Neurologists or Neurophysiologist or the equivalent or Ph.D. level Electroencephalographers.

- We recommend placement of electrodes in accordance with the 10.20 International System.

## 3.0 Technological Characteristics

The fundamental technical characteristics of the PANBUS Devices are the same as those of the predicate WARATAH Devices. Both apply analog to digital conversion technology to record EEG and polysomnography signals. These signals are transmitted over cables to a computer. The computer contains an interface card to interface the received signals to the computer.

Both are OEM device components supporting the creation of EEG Recording Systems. Application Programmer Interface software is available to support the creation of an EEG recording system.

## 4.0 Data Summary

Testing of the modifications was performed in compliance with the LaMont Medical, Inc. design control process. Testing included:

1. Testing to recognized consensus standards,
2. Software verification and validation,
3. Hardware verification of design output meeting design input requirements,

Testing is completed. No safety or effectiveness concerns remain.

## 5.0 Conclusions

The safety and effectiveness of use of the PANBUS Devices as a modification of the WARATAH Devices was demonstrated by testing in compliance with the Design Control process. The intended use and technology of the PANBUS Devices are the same as the predicate WARATAH Devices. No new questions of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LaMont Medical, Inc.
c/o Mr. Gary Syring
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

APR - 9 2012

Re: K042364
Trade/Device Name: PANBUS® Digital EEG and Sleep Acquisition Devices
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: OLV, GWQ
Dated (Date on orig SE ltr): August 26, 2004
Received (Date on orig SE ltr): August 31, 2004

Dear Mr. Syring:

This letter corrects our substantially equivalent letter of September 30, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K042364

Device Name: PANBUS® Digital EEG and Sleep Acquisition Devices

Indications for Use:

- For long term unattended EEG or other electrophysiological signal monitoring and recording.
- This device is intended for use by physicians skilled in electroencephalography. These individuals are typically Board Certified Neurologists or Neurophysiologist or the equivalent or Ph.D. level Electroencephalographers.
- We recommend placement of electrodes in accordance with the 10.20 International System.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Melkerson

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K042364